K024015

MAR 0 4 2003

ALLIANCE
MEDICAL CORPORATION

# PART B: 510(k) SUMMARY

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**Submitter:** Alliance Medical Corporation
10232 South 51st Street
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**Contact:** Moira Barton
Regulatory Affairs Specialist
(480) 763-5300 (o)
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**Date of preparation:** November 25, 2002

**Name of device:** *Trade/Proprietary Name:* Reprocessed Endoscopic Trocars and Cannulas
*Common or Usual Name:* Endoscopic Trocars and Cannulas
*Classification Name:* Endoscope and Accessories

**Predicate device(s):**

| | |
|---|---|
| **K901407** | Core Dynamics® Laparoscopic Trocar |
| **K911813** | Core Dynamics® Laparoscopic Trocar |
| **K950457** | Core Dynamics® Laparoscopic Trocar |
| **K932022** | Core Dynamics® Entrée Thoracoscopy Cannula Set |
| **K953409** | Core Dynamics® Laparoscopic Trocar |
| **K953903** | Core Dynamics® Laparoscopic Trocar |
| **K903419** | United States Surgical, Disposable Trocar and Sleeve |
| **K900487** | United States Surgical, Modified Auto Suture Surgiport Torcar and Sleeve |
| **K890818** | United States Surgical, Auto Suture Disposable Sugical Trocar |
| **K862611** | United States Surgical, Sterile Disposable Trocar-Sleeve Devices |
| **K963115** | United States Surgical, Trocar Cannula |
| **K945457** | United States Surgical, Trocar (Accessory) |
| **K931111** | Ethicon Endopath® Disposable Flexible Surgical Cannula |
| **K963760** | Ethicon Endo-Surgery, Inc., Non-Shielded Surgical Trocar |
| **K971738** | Ethicon Endopath® Trocar System |
| **Unknown** | AppleMed Trocar & Cannula model 900-800, 900-840, 900-860 |

**Device description:** Endoscopic Trocars and Cannulas are designed to establish a port of entry for endoscopic instruments used during minimally invasive surgery. Surgical Endoscopic Trocars and Cannulas are available in a variety of configurations and materials as well as trocar and cannula sets. Trocar seals vary between single-port and multi-port seals.

| | |
|---|---|
| **Intended use:** | The Endoscopic Trocars and Cannulas are intended for use during minimally invasive surgery for temporary dilation access to the abdominal and thoracic cavities for passage of diagnostic, therapeutic and operative instruments into the abdominal and thoracic cavities, and for percutaneous access to hollow body organs. |
| **Indications statement:** | Reprocessed Endoscopic Trocars and Cannulas are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures. |
| **Technological characteristics:** | The design, materials, and intended use of the Reprocessed Trocar and Cannulas are identical to the predicate devices. The mechanism of action of the Reprocessed Trocar and Cannula is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. |
| **Performance data:** | Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Trocar and Cannulas.<br><br>• Biocompatibility Testing<br>• Validation of reprocessing<br>• Sterilization Validation<br><br>Performance testing demonstrates that Reprocessed Trocar and Cannulas perform as originally intended. |
| **Conclusion:** | Alliance Medical Corporation concludes that the modified device (the Reprocessed Trocar and Cannula) is safe, effective and substantially equivalent to the predicate devices as described herein. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Ms. Moira Barton
Regulatory Affairs Specialist
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K024015
Trade/Device Name: Alliance Medical Corporation Reprocessed Endoscopic Trocars and Cannulas
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: December 3, 2002
Received: December 4, 2002

Dear Ms. Barton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# II. Indications for Use Statement

**510(k) Number (if known):**

**Device Name:** Alliance Medical Corporation Reprocessed Endoscopic Trocars and Cannulas

**Indications for Use:** Reprocessed Endoscopic Trocars and Cannulas are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use ____
(per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024015